

# Exhibit B

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA

United States of America, et al.,  
v.  
Gilead Sciences, Inc. ) Case Number:  
 ) Civil No. 17-cv-3523

## Rebuttal Expert Report of Virginia B. Evans

## I. Introduction

I have been engaged by the law firm Miller Shah LLP to review the May 3, 2021 Expert Report of Kevin G. McAnaney ("McAnaney Report") pertaining to the effectiveness of the compliance program of Defendant, Gilead Sciences, Inc. (hereinafter "Gilead" or "the Company") with respect to the Speaker Programs and Roundtables, (collectively, "Speaker Programs") and Advisory Boards ("Ad Boards"), which Gilead conducted from January 2013 through December 2019 (the "Review Period") for its two Hepatitis B Virus ("HBV") drugs, Viread and Vemlidy.

As explained in this Rebuttal Report, Mr. McAnaney's conclusions are largely based on the existence of certain compliance policies and procedures within Gilead that applied to Speaker Programs and Ad Boards during the Covered Period. The mere existence of policies and procedures, however, did not ensure that Gilead had an effective compliance program. Indeed, noticeably absent from the McAnaney Report is any discussion of the important policies and procedures that Gilead did not have in place, as well as any meaningful analysis of the significant facts which demonstrate that Gilead did not effectively implement its compliance policies and procedures . These failures render the conclusions in the McAnaney Report incorrect. I reach the findings and conclusions in this Rebuttal Report to a reasonable degree of certainty in the field of health care compliance.

## II. Summary

The McAnaney Report concludes that, at all times during the Review Period, Gilead maintained an effective compliance program that was consistent with, conformed to, or exceeded the standards of business and industry guidance. The evidence in this case does not support this conclusion.

Although Gilead had certain compliance policies in place, some of which were facially adequate recitations of existing compliance standards concerning Speaker Programs and Advisory Boards, Gilead's own employees and other witnesses testified during their depositions that, in practice, the compliance policies were not effectively implemented. Gilead employees often ignored the compliance policies and were not disciplined for doing so and even employees who purportedly attempted to be compliant, failed. Gilead's management ignored and sometimes encouraged compliance breaches in favor of increased sales and keeping the professional speakers ("Speakers"), who were paid honoraria to "present" at Speaker Programs, happy so that they would write Gilead prescriptions at high levels. The documents and testimony I reviewed confirm these facts.

The McAnaney Report does not attempt to address the inherent conflict between the business conduct manual's ("BCM") limitations on appropriate attendees at Speaker Programs and the composition of the actual attendees. Although the BCM policies limited targets and invitees to those HCPs who, by the nature of their practice, were reasonably likely to prescribe Viread and

Vemlidy, the actual attendees at the Speaker Programs regularly and predominately included virtually anyone in what Gilead therapeutic specialists ("TSs" or "Sales Representatives") considered to be the "continuum of care." This was true even though many of these individuals were not prescribers and many did not even meet Gilead's own definition of HCPs and were clearly not appropriate attendees under Gilead's own policies.

The McAnaney Report further fails to address the fact that Gilead's managers in the marketing ("Marketing") and sales ("Sales") units, and TSs, were given an extraordinary amount of discretion regarding compliance with specific Speaker Program and Ad Board policies in the BCMs. For instance, in practice, Gilead allowed its Sales and Marketing personnel to use their discretion about whether they would report noncompliance by Speakers, TSs, or other Gilead employees. The BCMs (the compliance policies) and the Business Conduct department ("Business Conduct") did not act as an effective check on this wide discretion.

Business Conduct was understaffed and uninvolved in the production of the actual Speaker Program and Ad Board programs. Although Business Conduct had access to ample information and data about the Speaker Programs, and sporadic input from Polaris Management Partners, LLC ("Polaris"), an outside monitor, Business Conduct did not conduct an organized, systematic compliance risk assessment or review of the Viread and Vemlidy Speaker Programs or Ad Boards. Such a compliance risk assessment would have

identified patterns of noncompliance leading to further investigation, remedial training, and other corrective actions. Business Conduct's failures prevented it from effectively addressing Speaker Program and Ad Board risks.

The McAnaney Report fails to address the fact Business Conduct did not use the results of the Polaris monitoring in a way that mitigated the risks that the Speaker Programs and Ad Boards were being misused to induce or reward prescribing behavior. Business Conduct did not conduct remedial training for Gilead employees who ignored its own compliance policies, let alone those who ignored industry standards<sup>1</sup> or guidance from the Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG"), Compliance Guidance for Pharmaceutical Manufacturers ("the Guidance").<sup>2</sup>

Despite the clear evidence found in emails and other documents that Marketing and Sales used the Speaker Programs to influence Speakers' prescribing behavior,<sup>3</sup> or as a reward for past prescribing, Business Conduct

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<sup>1</sup> The Pharmaceutical Research and Manufacturers of America ("PhRMA") Code on Interactions with Health Care Professionals, effective July 2002; available at [www.ucsfmcme.com/physician/PhRMACode.pdf](http://www.ucsfmcme.com/physician/PhRMACode.pdf) ("2002 PhRMA Code"); PhRMA Code on Interactions with Health Care Professionals, revised effective January 2009, §§6-7; [http://phrma-docs.phrma.org/sites/default/files/pdf/phrma\\_marketing\\_code\\_2008.pdf](http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf) ("2009 PhRMA Code").

<sup>2</sup> Department of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23732-23733 (May 5, 2003) (the "OIG Guidance").

<sup>3</sup> Deposition of Marc Aquino, August 25, 2020, Ex. 14, GP 00025288, 216:15-25, 217:19-218:23 (a TS states in a Vemlidy Business Planning Spreadsheet that she

remained oblivious to the risks this raised, or otherwise elected to ignore them. I found very little documentation that any TSs (or their managers, Regional Directors, or Marketing) were investigated or disciplined for failure to comply with basic compliance principles.

In short, contrary to the conclusions in the McAnaney Report, it is my opinion that Gilead's compliance program failed to protect against the risks that the Speaker Programs and Ad Boards would be misused to induce Speakers and Ad Board participants to write Viread and Vemlidy prescriptions.

### **III. The Sales and Marketing Business Goals Took Precedence Over Compliance.**

Although, as the McAnaney Report notes, the BCMs and other compliance documents contained sections covering Speaker Programs and Ad Boards, in practice, the TSs, sales and marketing managers, and Speakers often failed to meet the BCM requirements or simply ignored them.

At other times, Gilead's management stretched the letter and interpretation of the BCM requirements so that they were no longer effective.<sup>4</sup> The deposition testimony, exhibits, and documents provided a strong impression that the Sales and Marketing departments were primarily determined to keep

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will "add him [Dr. Regenstein] as a Speaker so when he speaks on it, he will start believing in the product more" and that she will "Add an HBV Speaker which will increase our relationship. Have him prescribe more Vemlidy.")

<sup>4</sup> Deposition of Chris Purcell, April 23, 2021, 620, 621, Ex. 13, REL 005294-95, Jan. 2018 email from Silician, Business Conduct Update (Lelani Larson split three presentations into nine to avoid the prohibition on the number of speaker programs an attendee could attend).

the Speakers and Ad Board participants happy so as to induce them to write Gilead prescriptions.

The compensation methodology of the Sales Representatives and their managers support this conclusion. Fully 60% of a Sales Representative's compensation was based on the prescriptions written in their territory (including those written by Speakers).<sup>5</sup> The Speaker Programs were a driver of the Sales Representatives' compensation. Encouraging the Speakers and Ad Board participants to write Viread and Vemlidy was important to the TSs and their managers.

#### **IV. In Practice, Speaker and Ad Board Participant Selections Were Based on Prescribing Patterns.**

Gilead's BCMs, as noted in the McAnaney Report, included policies regarding the selections of Speakers and Advisors based on their qualifications. Specifically, the BCMs stated that Sales and Marketing were not supposed to use selection as a way to reward or induce the prescription, use, or recommendation of Gilead products.<sup>6</sup> However, it is clear that the Sales and Marketing business units used candidates' Viread and Vemlidy prescribing

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<sup>5</sup> Deposition of Erica Chien, April 29, 2021, 67:14-68:5.

<sup>6</sup> See, for example, 2016 Gilead Business Conduct Manual, GP 00000388-390, and Business Conduct Update and Reminders, Silician, Foster City, Feb. 2016, GP 00132468 and GP00132493.

patterns (and the hope of increased prescribing) to recommend Ad Board participants and Speakers.<sup>7</sup>

For example, Gilead used the prescribers' market share and prescribing information to characterize health care professionals ("HCPs") as Loyalists, Splitters, and Dabblers. They used these categories, *inter alia*, to determine which HCPs to select as Ad Board participants or Speakers.<sup>8</sup> The Sales Representatives, their managers, Marketing, and upper management all used this same language to describe the prescribing physicians as potential Speakers or Ad Board participants throughout the Review Period.

**V. Sales and Marketing Tracked the ROI for the Speakers and Ad Board Participants Despite Prohibitions.**

The McAnaney Report references the fact that the BCMs outlined the acceptable purposes for Ad Boards, Speaker Programs and Speaker selection. The Gilead Speaker Bureau was supposed to train medical professionals to speak for Gilead. It was not supposed to serve as a mechanism to establish,

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<sup>7</sup> Deposition of Leilani Larson, Sept. 4, 2020, 168:14-170, Ex. 12, GP 00039924; Larson Dep. 182:4-185:11, Ex. 17, GP 00024142-143, Nov. 13, 2013, email from Larson to Richardson (invite Dr. Iskandarani, a Viread loyalist, to Speaker Training because he receives a large number of referrals from the Haitian community and he could be a strong voice promoting Viread's benefits to reach a significant market share.)

<sup>8</sup> Larson Dep. Ex. 28, GP 00105854, Mar. 12, 2015 Tang email to Larson (2014 sales data for current Speaker Bureau); Larson Dep. 236:16-240:1; Larson Dep. Ex. 29, GP 00083391, May 24, 2016, Larson email to Schmalzle (faculty for Ad Board should be "Splitters"); Larson Dep. 244:1-245:14.

maintain, or develop a relationship with a prescriber, or to gain access to Speaker Program participants.<sup>9</sup>

Speakers were not supposed to be nominated or selected based on the hope or understanding that they would prescribe, purchase, or recommend Gilead products. For these reasons, the Gilead BCMs purportedly did not allow a return on investment (“ROI”) analysis of the Speakers.<sup>10</sup> However, like other compliance rules, this prohibition was essentially meaningless as it was not followed in practice.

At Gilead, tracking the prescriptions of Viread and Vemlidy prescribers, and the prescriptions written for competitive drug products was routine.<sup>11</sup> This information was used by Sales and Marketing for various purposes.<sup>12</sup> For example, Gilead tracked the prescribing patterns of the Speakers and other prescribers in each TS’s territory to determine their compensation (and their manager’s compensation).<sup>13</sup>

Gilead analyzed the potential Speakers and Ad Board participants based on their prescribing patterns to determine if they were suitable candidates to

<sup>9</sup> See, for example, 2016 Business Conduct Manual, GP 00000394-396.

<sup>10</sup> *Id.*

<sup>11</sup> Deposition of Ilija Zlatar, Nov. 11, 2020, 71:10-25, 73:1-7.

<sup>12</sup> Aquino Dep., 179:3-25, 180:1-8, Ex. 5, GP00040240-44, June 2017 (plans to visit Speakers identified by Vemlidy market share.)

<sup>13</sup> Deposition of Catherine Chan, April 29, 2021, 43:16-44:5, 45:2-6; Chien Dep. 270:1-10, 278:21-279:12 (Speaker’s prescriptions were counted in TS’s territory to count the overall prescriptions written; 60% of TS’s compensation was based on the total prescriptions written in their territory).

serve as Speakers or on Ad Boards. It also tracked the prescribing patterns and market share for the Speaker Program attendees for six months before and after each program.<sup>14</sup> Gilead tracked the ROI of attendees and noted increases in the amount of prescriptions written.<sup>15</sup> When it tracked the ROI of the Speaker Program attendees, it captured and tracked the prescribing patterns of Speakers who were attendees at each other's Speaker Programs.<sup>16</sup>

Gilead also tracked the ROI for Speaker Programs including at least one ROI analysis for the Viread and Vemlidy Speaker Programs in 2015.<sup>17</sup>

Gilead did not follow its own policies regarding the prohibition on determining a Speaker's ROI or tracking their prescriptions.

## **VI. Sales and Marketing Used the Speaker Programs and Ad Boards to Induce Viread and Vemlidy Prescribing Despite BCM Prohibitions.**

Being nominated to the Speaker Bureau was lucrative for the Speakers who could make up to \$100,000 a year from Speaker Programs.<sup>18</sup> Participation

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<sup>14</sup> Larson Dep. Ex. 2, GP 00018343 (2017 tracking of potential Ad Board members); Ex. 26, GP 0105772 and 0105773, Larson Dep., 236:16- 240:1; Deposition of Tana Sartinoranont, Aug. 27, 2020, 73:6-76:16.

<sup>15</sup> Chien Dep., 181:5-23, 183:18-184:6.

<sup>16</sup> Larson Dep., 232:11-25; see also GP 00066447, 2016 Hepatitis B Speaker Education Program, Oct. 29, 2016, at p. 123 (Speakers can attend Speaker Programs 2 times a year on topics for which they are speaking, and 3 times a year on topics for which they are not speaking).

<sup>17</sup> Larson Dep., 38:1-12 (there was one ROI report that Larson could recall, prepared by the internal Sales analytics team.)

<sup>18</sup> Chien Dep., 252:7-253:12 (Speaker cap was \$100,000 for Speaker Programs only, until 2015 when the Speakers could also receive money for Ad Boards, thereby increasing the amount of money a Speaker who was an Ad Board participant could receive).

in the Ad Boards also enriched the participants. Despite testimony from Gilead 30(b)(6) witness Erica Chien that Sales Representatives were not involved in the Speaker or the Ad Board selection process;<sup>19</sup> in fact, the Sales Representatives did communicate with Marketing, either directly or through their managers, about nominating the Speakers in their territory. Sales and Marketing managers confirmed this during deposition testimony.<sup>20</sup>

**VII. In Practice, the Sales Representatives and Their Managers Assessed Business Need for the Speaker Programs Instead of the Marketing Department.**

According to Erica Chien, Gilead's 30(b)(6) witness, TSs and their Regional Directors should not have been involved in the business needs assessment for the Speaker Programs conducted each year because this was a Marketing function.<sup>21</sup> The reason for this rule is because the TSs and their managers were compensated in large part based on meeting Sales goals that relied on prescriptions written by the same Speakers who were nominated for the Speaker Bureau. It was natural for Sales Representatives to want prescribers in their

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<sup>19</sup> Chien Dep., 270:14-271:4, 329:4-19.

<sup>20</sup> Deposition of Graham Warden, Sept. 23, 2020, 50:19-54, Larson Dep. 167:22-168; Zlatar Dep. 67; Aquino Dep. 183:18-25, 184-186; Ex. 6, GP 00027064, email from Homer to Aquino, June 28, 2015 (TS identifies Dr. Moonka, a Speaker, committed that Vemlidy will be his "first choice for all appropriate patients"); Aquino Dep. 216-217:19-25, 218, Ex. 14, GP 00025288 (the TS states that "I am going to add him [Dr. Regenstein] as a Speaker so when he speaks on it, he will start believing in the product more.")

<sup>21</sup> Chien Dep., 195:25-196:19, 196:25, 197:1-3 (TSs could provide information about general education needs but determining the needs assessment for Speaker Program in a territory was a Marketing function).

territories to obtain a Speaker Bureau position because this would increase the TS's compensation as the Speaker's prescriptions and market share increased.

However, despite language in the PhRMA Code and OIG Guidance stating that there must be a legitimate need for the Speaker's or Ad Board participant's services beyond inducing or rewarding prescriptions, and despite the BCM policies referenced in the McAnaney Report that the number of Speakers should be limited to those necessary to satisfy a business need, the Sales Representatives, their managers, and the Regional Directors drove the business needs assessment. Marketing relied on Sales, including the TSs, to determine the number of Speakers needed in a geographic area or territory.<sup>22</sup>

Gilead had no quantitative measure to determine whether there was a business need for a Speaker Program or a Speaker.<sup>23</sup> As Ms. Chien testified, the Sales Regional Directors and TSs ("the floor level") should not have been involved in the business needs assessment because Marketing had access to the target numbers (prescribers) based on an algorithm used to create Gilead's business Plan of Action ("POA"). Ms. Chien testified that Sales personnel were only permitted to provide information to Marketing about an "assessment of general education need."<sup>24</sup>

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<sup>22</sup> Deposition of Jeremy Schmalzle, Sept. 25, 2020, 87-88:1-19, 89:5-15, 90:21-25, 91; Deposition of Jane Wu, March 19, 2021, 223:16-224:6, Ex. 8, GP 00045087.

<sup>23</sup> Schmalzle Dep., 54:1-21.

<sup>24</sup> Chien Dep., 195:25-197:3.

Despite this rule, in practice, the TSs defined an “educational need” whenever they wanted to host a Speaker Program to meet their own target (prescriber) goals; “it ultimately comes down to the person that’s going... that’s hosting the dinner.”<sup>25</sup>

It is clear that in practice the Sales Representatives (and sometimes the Speakers themselves) drove the business needs assessment for Speaker Programs.

### **VIII. The BCM Attendance Rules Were Ineffective at Preventing Abuse of the Speaker Programs.**

Speaker Program attendance issues also demonstrated that BCM policy (while present in written form) and Business Conduct were ineffective at controlling Speaker Program risks.

These attendance issues were:

- A. The presence of attendees at Speaker Programs who were guests, non-prescribers, or individuals for whom the on-label message was not relevant.<sup>26</sup>
- B. The absence of attendees resulting in payments to the Speaker for programs where less than four individuals were in attendance (and Gilead got less than is bargained for).
- C. Repeat attendance where physicians in the Speaker Bureau attended multiple programs on the same topic they qualified for,

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<sup>25</sup> Schmalzle Dep., 54:1-21; Wu Dep. 257, 259-261, Ex. 11, GP 44880 (TS raises in an email that Speaker Dr. Ted Kim wants to speak at an additional Speaker Program and seeks additional money in the budget (to keep Dr. Kim happy) and explains that she also “promised one talk for Dr. Rustgi.”)

<sup>26</sup> Zlatar Dep. 169-171, Ex. 11, GP 00201022-23, Melissa Kommey email to Regional Directors, April 16, 2014 (many attendees at roundtable were “unreportable.”)

presented by different Speakers, or the HCP attendees going to multiple programs well after they had an educational value.

The BCM specified that Gilead-approved invitations should be directed to HCPs who by the nature of their practice area are likely to prescribe the product(s) being promoted for on-label uses.<sup>27</sup> Ms. Chien testified that the HBV franchise was treated no differently than other franchises, that there were “no unwritten rules” for the HBV franchise,<sup>28</sup> and that the BCM rules on who qualified as a legitimate attendee did not change over the Review Period.

Nevertheless, Gilead’s witnesses, from senior management to the TSs disregarded the parameters set forth in the BCM as to who qualified as a legitimate attendee in order to justify the manner in which the Speaker Programs plainly operated – that is, the attendees often, and in many cases predominantly, included non-prescribers. Based on the prevalence of non-compliant attendees, it is clear that Business Conduct did not enforce its own policies regarding attendance at Speaker Programs. Even those employees who purported to take compliance seriously, had inappropriate attendees at their Speaker Programs.<sup>29</sup>

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<sup>27</sup> Section 2.3 of Gilead’s Speaker Program Policies. GP 00000084; GP 00000246; GP 00000558; GP 00000402-403; GP 00000710-711; GP 00000948-49; GP 00327103. Chien Dep., 161:15-162:12, 163:8-24.

<sup>28</sup> *Id.*, 34:14-22.

<sup>29</sup> Deposition of Samuel Lee, May 22, 2021 (Rough), 116:15-117:2, 119:17-24, 137:17-25 (Despite the fact that Mr. Lee raised compliance concerns regarding Speaker Programs with Gilead about another Gilead Sales Representative, and resigned from Gilead as result, he admitted to having inappropriate attendees attend at least one of the Speaker Programs he hosted.)

Gilead's deposition testimony revealed that senior management in Sales and Marketing apparently believed that Business Conduct checked the Speaker Program attendance sheets to make sure that all the attendees were appropriate.<sup>30</sup> This was an incorrect assumption.<sup>31</sup> The TSs hosting the event were responsible for filling out the attendance sheets and providing information about the credentials of the attendees. The TSs sometimes left this information blank and there is even testimony that the attendance sheets may have been falsified.<sup>32</sup> Relying on the TSs to ensure that all attendees were appropriate was an ineffective compliance control because they had an incentive to keep the prescribers happy.

#### **IX. The BCM Policies About Speaker Caps, Fair Market Value for Honoraria, Venues, and Modest Meals Were Often Ineffective.**

Gilead written compliance policies were often ineffective because exceptions could be made in the form of waivers. These waivers were granted by the business units and approved by Business Conduct in several different areas.

One example of waivers rendering a policy ineffective is Gilead's treatment of written compliance policies related to Speaker Caps. The PhRMA

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<sup>30</sup> Deposition of David L. Johnson, Aug. 31, 2020, 118:9-14 (Mr. Johnson believed that Business Conduct reviewed the sign-in sheets and would alert Sales managers if someone attended who was not a "standard attendee or target.")

<sup>31</sup> Chien Dep., 145:11-17 (there was no policy requiring Business Conduct review of the sign-in sheets.)

<sup>32</sup> Lee Dep., 192:21-193:25.

Code recommends that payments to Speakers be capped each year.<sup>33</sup> Gilead had policies capping payments to Speakers at \$100,000. However, in 2015, Gilead modified its rules so that a Speaker could receive \$100,000 for Speaker Programs, as well as additional money for Ad Boards or other consulting arrangements. This allowed Gilead to pay HCPs more than \$100,000.<sup>34</sup>

Another example of an ineffective compliance policy was the waiver of the fair market value ("FMV") requirement for Speaker honoraria (in 2017, five HBV Speakers were approved for a FMV exception to their honoraria rate and one physician, Dr. Zhang, was allowed an exception over that approved increase).<sup>35</sup>

Gilead also made routine exceptions to the venue and modest meal policies. The BCMs provided that the maximum expense per HCP for dinners outside of the office was \$125.<sup>36</sup> Meals were supposed to be modest by local standards (as per the PhRMA Code)<sup>37</sup> and provided only on an occasional basis. The venues for the Speaker Programs were supposed to be held in private rooms conducive to an educational atmosphere with appropriate audio-visual capabilities.

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<sup>33</sup> 2009 PhRMA Code, *id.*, Section 7, Speaker Programs and Speaker Training Meetings, p. 10.

<sup>34</sup> Chien Dep., 253:8-254:20.

<sup>35</sup> Johnson Dep. 160:12-25, 161, Ex. 4, GP 00018335-36.

<sup>36</sup> 2014 Gilead BCM, GP 00000205-206.

<sup>37</sup> 2009 PhRMA Code, *id.*

Review of the events demonstrated that Sales personnel did not follow these policies. Speaker Programs were often held at high-end restaurants and appeared to be social gatherings.<sup>38</sup> There are scant examples of managers actually disciplining the TSs for overages beyond occasional “coaching,” much less routine referrals to Business Conduct for further review and corrective action.

I also found no evidence that Gilead consistently tracked the amount spent for meals and beverages for its attendees on an annual basis.<sup>39</sup> The written “occasional” meal policy was not tracked or enforced.<sup>40</sup>

**X. The BCM and Business Conduct Department Were Ineffective Because in Practice There Was No Discipline for Violating the BCM Policies.**

Although the McAnaney Report is correct that the BCMS contained written policies requiring all Gilead personnel to report violations of the compliance policies, in practice, the TSs had the responsibility to police themselves and the Speakers.<sup>41</sup> Not surprisingly, given the incentives the TSs had for ensuring that prescribers in their territories (including Speakers) wrote Gilead prescriptions, there were few reports of compliance violations made

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<sup>38</sup> See, for example, Monitoring Spreadsheets, 2015 meeting 8040056, GP 00006183; and 2017 meeting 00005392, GP 00006188-89; IQV-Gilead 064674-76; IQV-Gilead 064577 (Speaker Program with 7 total attendees, including 2 Gilead employees, and a bill of \$2,758.99).

<sup>39</sup> Chien Dep., 226:10-16, 229:12-16.

<sup>40</sup> Chien Dep., 226:6-14 (“occasional” meals not defined); 21:18-19 (PhRMA Code did not define “modest meals.”)

<sup>41</sup> Zlatar Dep. 86:7-25 (not clear when reporting of noncompliance was necessary); 103:9-13 (as Regional Director, he did not go to Speaker Programs to monitor compliance.)

management or to Business Conduct. The compliance policies had no "teeth."<sup>42</sup>

Business Conduct was understaffed during the Review Period. The entire Business Compliance team involved in the HBV franchise was about 6 attorneys, with only one devoted full time to HBV.<sup>43</sup>

In large part, Business Conduct expected the Sales Representatives who hosted the event to determine if a Speaker Program was compliant. Business Conduct relied on the discretion of the Sales Representatives and their managers to report noncompliant programs, or whether to elevate compliance issues to a Regional Director (Sales).<sup>44</sup> This was not an effective compliance control.

In 2018, Gilead "formalized" its reporting and investigation protocol. However, prior to that time, there was no formal decision-making process around compliance complaints.<sup>45</sup> There were only approximately six investigations of Speaker Programs during the entire Review Period from 2013 through 2019, and of these, only one resulted in a warning letter.<sup>46</sup> There were no investigations of Ad Boards during this time despite the fact that Gilead

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<sup>42</sup> Lee Dep., 298:4-25, 300:13-25 (compliance program was lacking in terms of monitoring/policing).

<sup>43</sup> Chien Dep., 311:15-18, 312:20-25.

<sup>44</sup> Chien Dep., 66:25-67:5, 74:23-75:4, 78:23-79:11, 81:5-11.

<sup>45</sup> Chien Dep., 94:19-96:1, and 116:2-10 (discipline was case by case prior to 2018).

<sup>46</sup> Chien Dep., 94:19-95:1, 97:6-14, 97:23-98:5.

conducted a large number of Ad Boards, which raised concerns in the mind of at least one employee.<sup>47</sup>

Relying on Sales leaders like Regional Directors to elevate noncompliant programs to Business Conduct was not an effective compliance control because those same leaders were dependent in part on the prescriptions written by the Ad Board participants and Speakers when their compensation was determined. Importantly, there was no formal process to elevate the results of a compliance investigation to the offending Gilead employee's manager.<sup>48</sup>

Despite Mr. McAnaney's citation of the termination of a TS (Bo Kwok), Ms. Chien testified that she did not believe there were any Gilead employees terminated during the Review Period for HBV Speaker Program compliance issues.<sup>49</sup> Ms. Kwok, in fact, received a warning letter in 2014 for failure to report all reportable health care providers,<sup>50</sup> but as a successful TS, she remained employed and remained a member of the President's Club until at least 2016. She was finally terminated after driving a company car without a license.<sup>51</sup>

Sales Representatives who hosted the Speaker Programs were responsible for policing the Speakers. This placed the TSs in an untenable position and was an ineffective compliance control. For example, even Speakers who skipped

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<sup>47</sup> *Id.*; Lee Dep., 304:9-20.

<sup>48</sup> Chien Dep., 109:5-14, 112:7-14.

<sup>49</sup> Chien Dep., 102:1-5.

<sup>50</sup> Zlatar letter to Kwok, April 4, 2012, GP 00277810.

<sup>51</sup> Pemberton letter to Schmalzle, Feb. 11, 2016, GP 00108282, GP 00108284; Johnson Dep., 174, 175:1-17.

slides<sup>52</sup> or promoted their own practices<sup>53</sup> were seldom disciplined for noncompliant behavior. Because Gilead depended on the TSs to police the prescribers in their territory, few cases of Speaker noncompliance were reported.<sup>54</sup>

If Gilead Sales and Marketing managers could take the position that compliance was discretionary and that the rules could be manipulated, there was no incentive for the floor personnel to comply, especially if their own compensation was judged by the number of prescriptions written by the Speaker or Ad Board participant.

#### **IX. The Failure to Conduct Effective Audits and Monitoring Rendered the Compliance Program Ineffective.**

Mr. McAnaney stated in his report that Gilead regularly monitored and audited its business units for compliance with its policies, laws, and regulations. This assertion is not supported by the evidence in this case. In my opinion one of the primary weaknesses of the Gilead compliance program as it related to the Viread and Vemlidy Speaker Programs and Ad Boards was its failure to

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<sup>52</sup> Chien Dep., 128:22-15, 129:1-23, 130:22-25, 131:1-10 (there was no policy specifying that the Business Conduct department should discuss noncompliance with hosting TS. This was a “judgment call” even in the case of skipped slides.)

<sup>53</sup> Purcell Dep., 282-286.

<sup>54</sup> Chien Dep., 102:12-103:12 (less than five Speakers removed for non-compliance and these were driven by Marketing).

implement a compliance risk assessment or meaningfully use the information and data available to mitigate risk.<sup>55</sup>

For example, Gilead did not appear to conduct internal auditing of the Viread and Vemlidy Speaker Programs, with the exception of a single audit in 2014.<sup>56</sup> This audit, which was apparently withheld on the basis of privilege, was relied upon by Mr. McAnaney to conclude that Gilead incorporated the findings from this audit to enhance Speaker Program implementation controls and consistency company-wide.<sup>57</sup> No such conclusion can fairly be reached.

Ms. Chien discussed having a monitoring unit within Business Conduct and referred to their interaction with the live monitors from Polaris. She described live monitoring by Polaris as the observation of an actual program and the review by the monitor of a Gilead-provided checklist of things to look for. According to Ms. Chien, Polaris also reviewed the close-out documents completed by the TSs, and the sign-in sheets.<sup>58</sup>

Polaris reviewed about 50 or so HBV Speaker programs over the Review Period. These reviews were carried out so infrequently that, in some instances, Sales Representatives were not aware they were being conducted at all.<sup>59</sup> And,

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<sup>55</sup> Aquino Dep., 118:1-11 (Exec. Director, Sales and Marketing since 2017 had no knowledge of any audits of HBV Speaker Programs).

<sup>56</sup> Chien Dep., 288:2-12, 291:1-7 (Ms. Chien thought that the audit “would be used” to inform guidance to the business units on Speaker Programs.)

<sup>57</sup> McAnaney Report, at p. 20.

<sup>58</sup> Chien Dep., 106:15-118:24.

<sup>59</sup> Lee Dep., 296:16-297:20, 297:25-298:3.

during the early part of the Review Period, any third-party monitoring that was conducted was announced ahead of time. Polaris would cite any problems with the Program through findings that were communicated, in some cases, to the Business Conduct monitoring team. In other cases, the close-outs were “high level” and did not require further discussion. Importantly, Ms. Chien testified that there was no policy requiring that Business Conduct discuss the results of the monitoring with the TS hosting the Speaker Program.<sup>60</sup>

Since the monitoring reports did not go to field Sales personnel, the Marketing department or a “high level” commercial business unit would review the reports.<sup>61</sup> I found no evidence that the Polaris monitoring reports were used to conduct further analysis, to support a probe sample by Business Conduct, or to track the Speaker Program patterns observed in the monitoring reports with respect to particular geographic regions, Speakers, or TSs. I expected to see some evidence that the Polaris reports were used to train the Sales team about the risks inherent in allowing a Speaker to skip slides, invite inappropriate attendees, or provide lavish meals to repeat attendees. I did not find documents supporting use of the Polaris monitoring to remediate risk.

Business Conduct ignored obvious compliance risks in the Polaris reports and other data. For example, the TSs were supposed to fill out the sign-in sheets and upload them into a computerized database but these were not sent to

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<sup>60</sup> Chien Dep., 119:7-15, 122:6-13, 126:16-127:7, 127:10-128:9, 128:22-25.

<sup>61</sup> Chien Dep., 143:5-10.

Polaris.<sup>62</sup> Polaris had no way of knowing if the attendees were legitimate attendees although several Polaris reports remarked on apparent inappropriate non-prescribers, family members, and other guests in attendance. In addition, Business Conduct did not review the appropriateness of the attendees, instead relying on the Sales Representatives to comply with the BCM policies.<sup>63</sup>

The sign-in sheets had a box for the TS to fill in the attendees' credentials or professional designation.<sup>64</sup> These were often blank because the TS did not fill the box in or used the term "other." There was no field for the TSs to explain why a particular attendee was appropriate.<sup>65</sup> Business Conduct did not systematically audit this information despite Ms. Chien's concern that a pattern of missing information would be a potential compliance concern.<sup>66</sup> Ms. Chien stated that Business Conduct relied on the Sales Representatives to use their discretion about who was appropriate.<sup>67</sup> There was no follow-up to see if the TSs were

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<sup>62</sup> *Id.*, 147:1-9.

<sup>63</sup> *Id.*, 150:21-151:3.

<sup>64</sup> *Id.*, 166:9-169:8.

<sup>65</sup> Chien Dep., 144:21-145:20.

<sup>66</sup> *Id.*, 174:17-175:9.

<sup>67</sup> *Id.*, 168:24-169:5 (Sales Representatives should not necessarily invite attendees from the Speaker's own practice because "the Program should not be directed to those folks, because we want to ensure the legitimacy of the Program, and that we're not just paying somebody to do what they would normally do during their course of business."); 169:24-170:7, 170:19-171:3 (the Sales Representative has the responsibility to ensure that all appropriate information is captured in the sign-in sheet.)

inviting inappropriate attendees, or how often they left boxes on the sign-in sheets blank.

I could find no evidence that Business Conduct tracked the number of times exceptions to the rules were granted for particular Speakers or attendees. Similarly, I found no evidence that Business Conduct reviewed the Sales Representative compensation methodology against the number of times the TS nominated or sought nomination of the high-volume Speakers and Ad Board participants in their territories.

Business Conduct did not test its compliance policies to see if they were working. It did not conduct data analytics to determine whether the compliance policies were being followed or whether the Speaker Programs and Ad Boards were being misused in practice. It did not conduct a comparative review of the length of time spent presenting medical and scientific information against the length of the dinner portion of the Speaker Programs.<sup>68</sup>

Business Conduct apparently did not review the Ad Board programs or invitations to ensure that they were nonpromotional. This should have been a concern especially at the time when Gilead switched from promoting Viread to promoting Vemlidy in 2016.<sup>69</sup>

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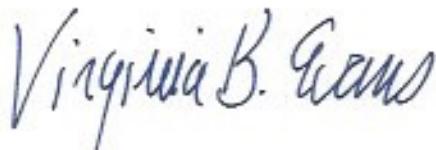
<sup>68</sup> Chien Dep., 137:19-138:1; 255:12-22, 258:12-259:1 (Ms. Chien incorrectly thought that the educational portion of a dinner program was about two hours.)

<sup>69</sup> Purcell Dep., 146-149 (concerns about an Ad Board being used to promote switch from Viread to Vemlidy relayed to Schmalzle), 314-316 (promotional presentations at Ad Boards with "plants or Loyalists" to encourage participants to use Gilead products.)

The Business Conduct department conducted no systematic compliance risk assessment of either the Speaker Programs or the Ad Boards despite significant information and documents indicating that in practice, these programs generated significant compliance risk.

For the foregoing reasons, and as detailed more fully in my initial Report, I disagree with the conclusions of the McAnaney Report. Although Gilead had certain compliance policies and procedures in place as it related to Speaker Programs and Ad Boards for Viread and Vemlidy during the Review Period, those policies were not sufficient and not implemented in a manner that resulted in an effective compliance program.

Respectfully submitted,



Virginia B. Evans, Esq.

May 26, 2021

**Documents Considered**

Materials identified as part of my May 3, 2021 report  
Expert Report of Kevin G. McAnaney 5-3-21  
Deposition of Chris Purcell 042321  
Exhibits to Deposition of Chris Purcell 042321  
Deposition of Erica Chien 042921  
Deposition of Erica Chien 043021  
Deposition of Catherine Chan 042921  
Deposition of Samuel Lee 052221 (Rough)  
IQV-Gilead-064577  
IQV-Gilead-064674-676